IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PACIRA BIOSCIENCES, INC.,	)	
Plaintiff,	)	**Case No.**
v.	)	**COMPLAINT FOR DAMAGES AND INJUNCTIVE RELIEF**
VENTIS PHARMA, INC., and INFUSYSTEM HOLDINGS, INC.,	)	**JURY TRIAL DEMANDED**
Defendants.	)	

Plaintiff Pacira BioSciences, Inc. ("Pacira"), brings this Complaint against Defendants Ventis Pharma, Inc. ("Ventis"), and InfuSystem Holdings, Inc. ("InfuSystem" and, collectively with Ventis, "Defendants"), and alleges as follows:

INTRODUCTION

1. This is a deeply troubling case in which Ventis, inflating its profits while potentially putting patients in grave danger with untested drug combinations, is claiming that its drug cocktail products are safe, effective, and approved by the Food and Drug Administration (the "FDA") (when they are none of those things), by falsely advertising, literally or impliedly, that its products are generic to or substitutable for, if not superior to, a category-leading pain drug product from Pacira.

2. In a world where patients and providers are desperate for pain relief alternatives to highly-addictive opioids, Ventis – and its marketing partner, InfuSystem – have engaged in a sustained campaign to promote Ventis' drug cocktail products as safe and effective opioid alternatives through demonstrably false and misleading advertisements – including blatantly

false statements that Ventis' drugs are safer and more effective than a product from Pacira, the first long-lasting non-opioid drug approved by the FDA to reduce post-surgical pain.

3. Pacira brings this suit to prevent Defendants from misleading consumers as they callously attempt to put profits over patient safety by falsely advertising and promoting drug cocktails that have never been approved by the FDA.

4. Accordingly, with this suit, Pacira aims to stop Ventis and InfuSystem from continuing their unlawful and willful false advertising practices, which have directly harmed Pacira and, in turn, have potentially put unsuspecting patients in harm's way.

Pacira's FDA-Approved EXPAREL® Product

5. Pacira is a leading provider of non-opioid pain management solutions.

6. Among other products, Pacira markets and manufactures EXPAREL®, the first long-lasting non-opioid drug approved by the FDA to reduce post-surgical pain.

7. EXPAREL® is injected at the surgical site during surgery or shortly thereafter to manage and reduce post-surgical pain for several days – all without the use of dangerous and addictive opioids.

8. The active ingredient in EXPAREL® is bupivacaine. EXPAREL® features a proprietary multivesicular liposome (pMVL) technology, which encapsulates bupivacaine in a suspension of multivesicular liposomes.

9. As a result of the process to secure FDA approval, EXPAREL® has undergone rigorous testing, studies, and analysis to confirm its efficacy and safety by the government and scientific community.

10. Prior to Pacira's development of EXPAREL®, costing millions of dollars over multiple years and requiring clinical trials to establish the safety and efficacy of this novel drug

product, the only options for patients to manage and reduce post-surgical pain for several days were catheter based "pain pumps" or dangerous opioids.

11. Pacira in EXPAREL® created an entirely new category of long acting parenteral analgesics with a current indication from the FDA for single-dose infiltration in patients aged six (6) years and older to produce post-surgical local analgesia and in adults as an interscalene brachial plexus nerve block to produce post-surgical regional analgesia that last longer than eight (8) hours (collectively, this new category of drugs is identified herein as the "Post-Surgical Non-Opioid Regional Analgesia Category").

12. EXPAREL® for over ten (10) years has been, by a significant margin, the leading product in the Post-Surgical Non-Opioid Regional Analgesia Category.

13. Pacira has spent substantial resources on its marketing efforts to educate the healthcare market (and broader public) on the benefits of the Post-Surgical Non-Opioid Regional Analgesia Category and, within this larger category, the use of EXPAREL® to treat post-operative pain.

14. Pacira's marketing and education efforts over the last decade have paid off.

15. The Post-Surgical Non-Opioid Regional Analgesia Category has grown significantly, as health care providers and consumers learn and understand the benefits of long-lasting non-opioid pain control. Indeed, within the Post-Surgical Non-Opioid Regional Analgesia Category, EXPAREL® has to date been used to treat over *10 million patients* across the United States.

Defendants' False Advertising And Unfair Competition
In Connection With The Sale Of Ventis' Unapproved Compounded Drug Cocktails

16. Ventis operates as the exclusive so-called "logistics administrator" for an outsourcing facility named Nubratori RX ("Nubratori"), which makes compounded drug

products. On information and belief, Ventis holds the rights to the compounded drug products that Nubratori has been licensed to compound.

17. On information and belief, InfuSystem maintains a partnership with Ventis as its marketing provider.

18. Defendants together advertise, market, offer for sale, and sell compounded drug products that are not approved by the FDA ("Unapproved Compounded Drug Cocktails").

19. The FDA defines compounding as a "practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."[1]

20. Unapproved Compounded Drug Cocktails do not go through the FDA's extensive new drug approval process, "which means [the] FDA has not evaluated their safety, effectiveness, or quality prior to marketing."[2]

21. As noted by the FDA, "[d]rugs that have circumvented regulatory safeguards may be contaminated, counterfeit, contain varying amounts of active ingredients, or contain different ingredients altogether."[3] As such, compounded drugs can present a significant risk to patients.

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[1] *Human Drug Compounding*, U.S. Food & Drug Admin., https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding (last visited Nov. 1, 2023).

[2] *FDA warns patients and health care providers about potential risks associated with compounded ketamine products, including oral formulations, for the treatment of psychiatric disorders*, U.S. Food & Drug Admin., https://www.fda.gov/drugs/human-drug-compounding/fda-warns-patients-and-health-care-providers-about-potential-risks-associated-compounded-ketamine (last visited Nov. 1, 2023).

[3] *Warning Letter: www.gorillahealing.com*, U.S. Food & Drug Admin. (Oct. 2, 2023), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/wwwgorillahealingcom-664245-10022023.

22. Furthermore, co-packaged drugs – such as the Unapproved Compounded Drug Cocktails – pose unique safety and efficacy concerns because, even if the substances have been approved individually, they may present unforeseen risks when used in combination with each other.[4]

23. The FDA has further stated that compounded drugs "do not have the same safety, quality, and effectiveness assurances as approved drugs," and as such, the "unnecessary use of compounded drugs unnecessarily exposes patients to potentially serious health risks" because "compounded drugs are not FDA-approved," meaning the "FDA does not verify their safety, effectiveness or quality before they are marketed."[5]

24. Notwithstanding these warnings from the FDA, Defendants advertise, market, and sell their Unapproved Compounded Drug Cocktails (sourced from Nubratori) as comparable to, and replacements for, Plaintiff's FDA-approved EXPAREL® bupivacaine product.

25. Recognizing the high and increasing demand for non-opioid analgesics, Defendants have and are marketing and selling new drugs for post-surgical relief in the Post-Surgical Non-Opioid Regional Analgesia Category – but without seeking let alone obtaining any FDA approval or completing any clinical trials to validate their safety and efficacy.

26. To circumvent FDA approval requirements established under the Federal Food, Drug, and Cosmetic Act ("FDCA") and flood the market with their illegal drugs as fast as

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[4] *See, e.g.*, Fixed-Combination and Co-Packaged Drugs: Applications for Approval and Combinations of Active Ingredients Under Consideration for Inclusion in an Over-the-Counter Monograph, 80 Fed. Reg. 79776, 79780 (Dec. 23, 2015).

[5] *Compounding and the FDA: Questions and Answers*, U.S. Food & Drug Admin., https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers (last visited Nov. 1, 2023).

possible, Defendants (advertising and selling Unapproved Compounded Drug Cocktails manufactured by Nubratori) purport to rely on a very narrow exemption to new drug approval requirements for drugs that are "compounded" by registered "outsourcing facilities." This carefully-circumscribed exemption is commonly referred to as the "503B exemption."

27. Under that exemption, a compounded drug may be manufactured and sold without FDA approval, but only if that drug is expressly identified on the FDA's drug shortage or clinical need lists.

28. Among other Unapproved Compounded Drug Cocktails they advertise and offer for sale, Defendants advertise and sell two Unapproved Compounded Drug Cocktails – named "Enduracaine" and "Endura-Kit" – in the Post-Surgical Non-Opioid Regional Analgesia Category, which products consist of epinephrine, tetracaine, and lidocaine for combined use.

29. Ventis and InfuSystem claim that Enduracaine and Endura-Kit meet the 503B exemption.

30. While these Unapproved Compounded Drug Cocktails have not been approved by the FDA, Defendants have distributed misleading advertisements and marketing materials that are intended to, and do, imply that the FDA has approved them.

31. Defendants falsely advertise the Enduracaine and Endura-Kit Unapproved Compounded Drug Cocktails by making statements that describe EXPAREL® and the benefits of the Post-Surgical Non-Opioid Regional Analgesia Category as established by and relying upon EXPAREL®, but are false or misleading as to the Enduracaine and Endura-Kit products.

32. Ventis and InfuSystem have made misleading statements in advertising and promotion that claim or imply that the Enduracaine and Endura-Kit Unapproved Compounded

Drug Cocktail products have been approved by FDA and/ or have been subjected to clinical trials.

33. Using these false and misleading advertisements, Defendants have knowingly induced healthcare providers to purchase the Enduracaine and Endura-Kit products based on misrepresentations of their efficacy, and on the mistaken belief that they have been approved by the FDA and/ or otherwise comply with the FDCA.

34. On information and belief, had healthcare providers known the Enduracaine and Endura-Kit products neither received FDA approval nor complied with federal law, they would likely have never purchased and used them. Using unapproved drugs that have not been evaluated for efficacy and safety presents inherent – and needless – risks to patient health and safety.

35. Pacira has been directly harmed – and continues to be harmed – by Defendants' unlawful conduct in the form of lost business, market share, sales, revenue, and profits, among other serious and ongoing harms. Indeed, Ventis and InfuSystem have used these false and misleading statements in advertisements and marketing materials – along with pricing its drugs well below EXPAREL® – to unlawfully compete against Pacira and harm its business in the Post-Surgical Non-Opioid Regional Analgesia Category.

PARTIES

36. Pacira is a pharmaceutical company incorporated under the laws of Delaware with its principal place of business in Tampa, Florida.

37. Ventis is incorporated in Delaware with its principal place of business in Newport Beach, California.

38. InfuSystem is a sales and marketing company incorporated in Delaware with its principal place of business in Madison Heights, Michigan.

JURISDICTION AND VENUE

39. The Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331 because Pacira asserts claims against Defendants under the Lanham Act, 15 U.S.C. §§ 1051, *et seq.*

40. The Court has general personal jurisdiction over Pacira because it is incorporated in Delaware.

41. The Court has general personal jurisdiction over Ventis because it is incorporated in Delaware.

42. The Court also has general personal jurisdiction over InfuSystem because it is incorporated in Delaware.

43. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(1) because Defendants reside in this District.

FACTS COMMON TO ALL CAUSES OF ACTION

FDA Approval Of Drug Products

44. The FDA has regulatory authority over the process for approving any "new drugs" that are developed for human use and consumption. 21 U.S.C. §§ 355 & 393(b).

45. To obtain approval of a new drug, an applicant must satisfy extensive application requirements that require substantial investments of capital and resources. *See id.* § 355(b).[6]

46. The FDCA provides a very narrow exemption to new drug approval requirements for drugs that are "compounded" by registered "outsourcing facilities." 21 U.S.C. § 353b.

[6] Bright Focus Foundation, *FDA Approval Process* (Sept. 2, 2021), https://www.brightfocus.org/clinical-trials/how-clinical-trials-work/fda-approval-process; *Development & Approval Process*, U.S. Food & Drug Admin., https://www.fda.gov/drugs/development-approval-process-drugs (last visited Nov. 1, 2023).

47. Under the Section 503B exemption, an outsourcing facility that compounds using bulk drug substances is exempt from the FDCA's new drug approval requirements if (1) the drug compounded from "bulk drug substances" appears on the FDA's drug shortage list ("Drug Shortage List"), or (2) if the "bulk drug substances" appear on the FDA's list of bulk drug substances for which it has determined there is a "clinical need" ("Clinical Need List"). 21 U.S.C. § 353b(a)(2)(A)(i)-(ii).

48. An outsourcing facility cannot satisfy the 503B exemption simply by combining FDA-approved drugs or "bulk drug substances" that are included on either list, or at varying dosages, to sell an unapproved compounded drug. *Id.* § 353b(a)(2)(A)(i)-(ii).

49. In other words, a compounder cannot meet the 503B exemption just by combining drugs or bulk substances on the lists to create a new combined product. *See id.*; 21 C.F.R. § 300.50.

50. Because compounded drug products under the 503B exemption are not FDA-approved, they have not undergone FDA premarket review for safety and efficacy, and thus pose more "significant risks" to the American public.[7]

Pacira's EXPAREL® Product

51. When first introduced to the market in 2011, EXPAREL® created an entirely new category of post-operative pain management products, the Post-Surgical Non-Opioid Regional Analgesia Category.

52. Pacira's analgesic product – liposomal bupivacaine – was a new formulation of bupivacaine intended for single-dose infiltration at the surgical site for post-operative analgesia.

[7] *FDA's Human Drug Compounding Progress Report*, U.S. Food & Drug Admin. 8 (Jan. 2017), https://www.fda.gov/files/drugs/published/Compounding-Safety-Report---2017.pdf.

53. Through this novel formulation, bupivacaine is slowly released from this liposomal vehicle and can provide prolonged analgesia at the surgical site without the use of opioids.

54. Prior to EXPAREL®, the most common analgesic for treating moderate to severe post-operative pain were opioid products, which present significant and undesirable side effects for patients, including addictive qualities.[8]

55. Opioid-minimizing strategies can enhance recovery after surgery. Multimodal analgesia, featuring Pacira's EXPAREL® product, uses multiple pain management modalities for more effective pain control, which can lead to enhanced clinical and economic benefits.

56. EXPAREL® works locally at the surgical site and uses a proprietary technology to cause bupivacaine to be released over time.

57. Pacira's product has been clinically proven to significantly reduce pain during the crucial seventy-two (72) hours following surgery, decrease opioid use, delay the time until and/or completely negate the patient's first opioid use following surgery, and improve patient satisfaction, as compared to other pain management products following a procedure.[9]

58. Pacira is the owner of U.S. trademark registration number 4,074,454, issued on December 20, 2011, for the mark EXPAREL® for "analgesics; preparation for the relief of pain; anesthetics for peri-operative and post-operative use; pharmaceutical preparations and substances

[8] *See* Mana Saraghi, DMD, et al., *Three Newly Approved Analgesics: An Update*, Anesth. Prog. 178–87 (Winter 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3891458/pdf/i0003-3006-60-4-178.pdf (last visited Nov. 1, 2023).

[9] *See* Stephen R. Gorfine, et al., *Bupivacaine extended release liposome injection for prolonged postsurgical analgesia in patients undergoing hemorrhoidectomy: a multicenter, randomized, double-blind, placebo-controlled trial*, Dis Colon Rectum. 1552–59 (Dec. 2011), https://pubmed.ncbi.nlm.nih.gov/22067185/ (last visited Nov. 1, 2023).

for use in anesthesia and for the treatment and control of pain; liposome formulations containing preparations and substances for use in anesthesia and for the treatment and control of pain."[10]

59. Pacira promotes and advertises its EXPAREL® product, and the unique attributes of multimodal analgesia featuring Pacira's EXPAREL® product, through various channels, including on the website exparel.com and to physicians and licensed healthcare professionals, among others.

60. Pacira's efforts to educate the healthcare market on the benefits of the Post-Surgical Non-Opioid Regional Analgesia Category have been significant and sustained, including employing a field-based Clinical Education team, conducting and/ or sponsoring over 1,023 educational didactic workshops, cadaver labs, and Continuing Medical Education (CME) programs since 2018, sponsoring and authoring hundreds of peer-reviewed publications, and creating scores of procedure-dependent clinical practice guides and videos.

61. Pacira undertakes considerable efforts to build trust and confidence in the EXPAREL® brand and of multimodal analgesia featuring Pacira's EXPAREL® product.

62. Pacira also invests significant time, money, and effort to advertise and promote its EXPAREL® products, spending millions of dollars each year on such efforts.

63. Pacira's advertising for its EXPAREL® product, dating back over ten (10) years, includes core print 'leave-behinds,' a robust speaker program series, and a web and digital presence. Pacira has also invested millions of dollars into nationwide sponsorships, such as sponsorships with the Special Olympics and NFL Players Association, among many others.

[10] *See* EXPAREL, No. 4074454 (issued Dec. 20, 2011), *available at* https://uspto.report/TM/77464815 (last visited Nov. 1, 2023).

64. As a result of Pacira's long use, promotion, and advertising of the EXPAREL® bupivacaine products, the EXPAREL® trademark is a well-known, strong, and famous mark, and became famous prior to any of the acts of Defendants complained of herein.

65. The combination of the highest quality products and extensive promotional activities have kept the EXPAREL® brand at the forefront of the post-surgical pain management practice for caregivers throughout the United States for over a decade, and has resulted in millions of dollars of sales year after year.

Defendants' Acts

66. Ventis promotes and sells the Endura-Kit product through a relationship with InfuSystem.

67. On information and belief, InfuSystem entered a National Sales and Marketing Agreement with Ventis, under which InfuSystem markets and sells the Endura-Kit product.

68. On information and belief, InfuSystem has participated in developing and distributing the false and misleading advertisements for the Endura-Kit product by Ventis, including the claims found on Ventis' website and the claims found in presentations, pamphlets, and other media distributed to health care providers regarding this Unapproved Compounded Drug Cocktail.

69. Defendants together advertise and make promotional claims about the Enduracaine and Endura-Kit Unapproved Compounded Drug Cocktails that are literally false and/ or impliedly false and misleading because these Unapproved Compounded Drug Cocktails, which are not FDA-approved, are not generic to or substitutable for EXPAREL® (as they, *inter alia*, do not have technology causing the bupivacaine to be released over time, do not provide pain relief for up to 72 hours, and do not have any clinical testing supporting their use) and are

not properly advertised, offered for sale, or sold in competition with EXPAREL® in the Post-Surgical Non-Opioid Regional Analgesia Category (as they, *inter alia*, do not have any safety or efficacy data).

70. On information and belief, Defendants advertise, offer for sale, and sell, the Enduracaine and Endura-Kit Unapproved Compounded Drug Cocktails as "opioid-free post-surgical pain relief" products.[11]

71. Defendants sell the Enduracaine and Endura-Kit products in the Post-Surgical Non-Opioid Regional Analgesia Category in direct competition with EXPAREL®.

72. The Enduracaine product consists of a syringe containing epinephrine and a vial containing tetracaine and lidocaine. Enduracaine is sold in a two-part injectable kit, which Defendants advertise and market as the "Endura-Kit" product.

73. Improper administration of any one of these component drugs can lead to chest pain, seizures, irregular heartbeat, and unusual bleeding.[12]

74. Despite these known risks to patient health and safety, and even though these Unapproved Compounded Drug Cocktails have not been approved by the FDA or undergone any clinical trials, Defendants nevertheless aggressively market and distribute them across the United States.

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[11] Ventis Pharma, *EnduraKit*, https://endurakit.com/ (last visited January 20, 2023).

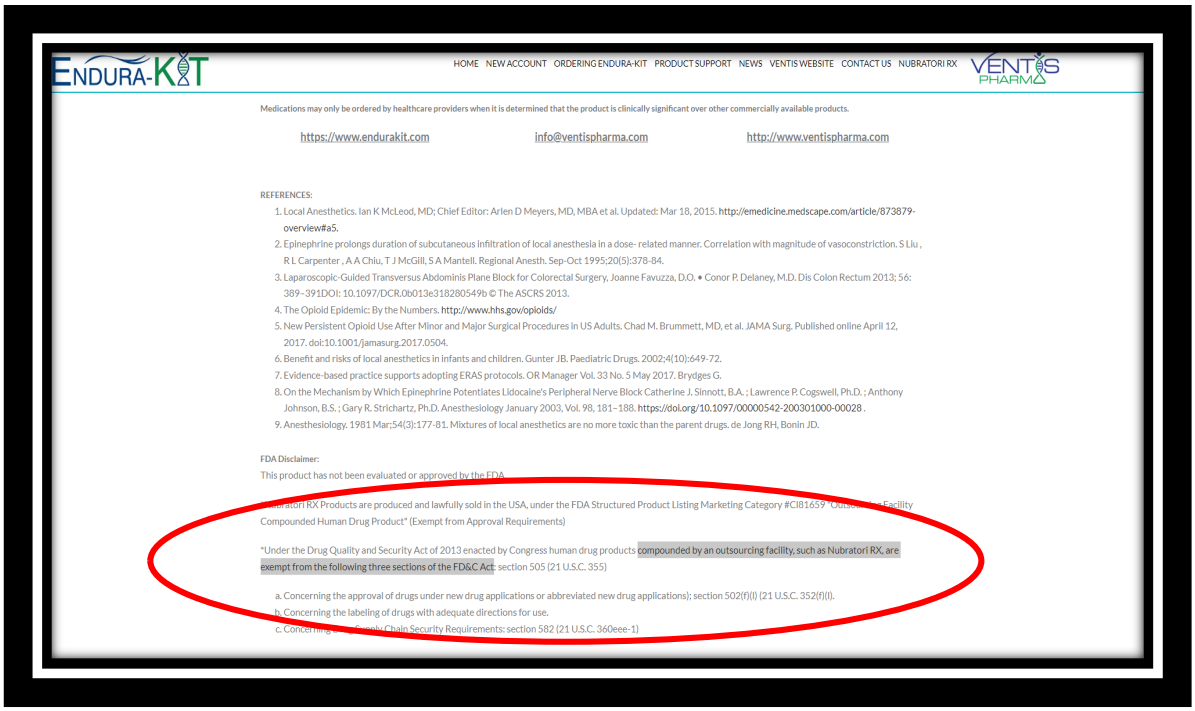
[12] Mayo Clinic, *Tetracaine (Topical Application Route)*, https://www.mayoclinic.org/drugs-supplements/tetracaine-topical-application-route/side-effects/drg-20072833 (last visited Nov. 1, 2023); National Institutes of Health, *Epinephrine*, https://www.ncbi.nlm.nih.gov/books/NBK482160/#:~:text=The%20more%20common%20side%20effects,vomiting%2C%20weakness%2C%20and%20tremors.&text=Careful%20monitoring%20of%20vital%20signs,especially%20in%20patients%20with%20polypharmacy (last visited Nov. 1, 2023); Mayo Clinic, *Lidocaine (Injection Route)*, https://www.mayoclinic.org/drugs-supplements/lidocaine-injection-route/side-effects/drg-20452273?p=1 (last visited Nov. 1, 2023).

75. In their advertising, Defendants offer for sale and sell the Enduracaine and Endura-Kit products as replacements for, or equivalent to, Pacira's EXPAREL® bupivacaine product.

76. The Unapproved Compounded Drug Cocktails offered for sale and sold by Defendants do not have the proprietary multivesicular liposome (pMVL) technology found in the EXPAREL® product.

77. The Enduracaine and Endura-Kit Unapproved Compounded Drug Cocktails do not provide pain relief for up to 72 hours.

78. Defendants claim the Endura-Kit Unapproved Compounded Drug Cocktail does not require FDA approval because it meets the 503B exemption. [13] A representative advertisement including such claim is set forth below:



[13] On information and belief, Ventis is in the process of completing US FDA IND tests and studies, plans to perform FDA clinical trials, and aims to later submit Enduracaine for review and approval by the FDA.

79. But neither Enduracaine nor Endura-Kit qualify for the 503B exemption. Neither product is on the Drug Shortage List. While the list identifies injections for two of the three active ingredients – lidocaine and epinephrine – the FDA has not included the *combination* of these three drugs on its list. Separately, tetracaine is altogether absent from the Drug Shortage List and has not received FDA approval for use as an injection.

80. Furthermore, neither the Enduracaine nor the Endura-Kit Unapproved Compounded Drug Cocktails nor their component bulk substances appear on the FDA's Clinical Need List.

81. While Ventis claims to rely on the 503B exemption to sell the Enduracaine and Endura-Kit products, its marketing and advertisements mislead the public to believe the FDA has approved these Unapproved Compounded Drug Cocktails.

82. For example, in a White Paper available on Ventis' website, Defendants have described Endura-Kit as an "off-label use version of Enduracaine." However, an "off-label use" is generally recognized as the use of an FDA-approved product for an unapproved use. Thus, Defendants' statement misleadingly suggests that Enduracaine is FDA-approved when it has not received any such approval.

83. Defendants have further placed advertising in *Anesthesiology News*, one of the most widely read publications among anesthesiologists, claiming that Endura-Kit is "produced following cGMP manufacturing guidelines under 503B outsourcing standards overseen by the FDA" and "made from a combination of currently FDA approved USP products." A copy of that advertisement is set forth below:

84. But the FDA does not oversee the production of Endura-Kit.

85. Likewise, Defendants' representation that the Endura-Kit Unapproved Compounded Drug Cocktails is "made from a combination of currently FDA approved USP products" is also false and misleading because the FDA has not approved the use of the drugs as combined in the product.

86. Still further, the advertisement brazenly makes the completely unsubstantiated claim that this Unapproved Compounded Drug Cocktail is "considered safe and acceptable for use." The FDA, however, has not reviewed or approved the Endura-Kit product, and there are no studies establishing the safety or efficacy thereof.

87. Defendants also tout in their advertising and marketing that Ventis' Unapproved Compounded Drug Cocktail provides an "EXTENDED DURATION" of treatment and pain-relief as compared to other drugs – necessarily including EXPAREL®, long the market-leading product in the Post-Surgical Non-Opioid Regional Analgesia Category. A representative copy of Defendants' advertising is set forth below:

88. That statement is false and misleading because Endura-Kit has not been reviewed or approved, or undergone any clinical trials to confirm its capabilities, efficacy, and safety.

89. On information and belief, Defendants make and distribute the same or similar claims at tradeshows and events.

90. In addition to "duration" claims about the Unapproved Compounded Drug Cocktails, Defendants also make advertising claims with untested and unverified statements about the capabilities, safety, and efficacy of the Endura-Kit product, a representative copy of which is provided below:

91. Ventis has no basis whatsoever to advertise its product as "Quick Onset," "Long Lasting," "Safe," or for "Pediatric Use." This Unapproved Compounded Drug Cocktail has not been reviewed or approved by the FDA, or undergone any clinical trials to confirm its capabilities, efficacy, and safety.

92. On information and belief, in claiming that the Endura-Kit product is "cost effective" Ventis is making a comparative claim against EXPAREL® in the Post-Surgical Non-Opioid Regional Analgesia Category.

93. In addition to their false and unsubstantiated claims about the Enduracaine and Endura-Kit Unapproved Compounded Drug Cocktail products themselves, Defendants make expressly or impliedly false comparative claims against EXPAREL®.

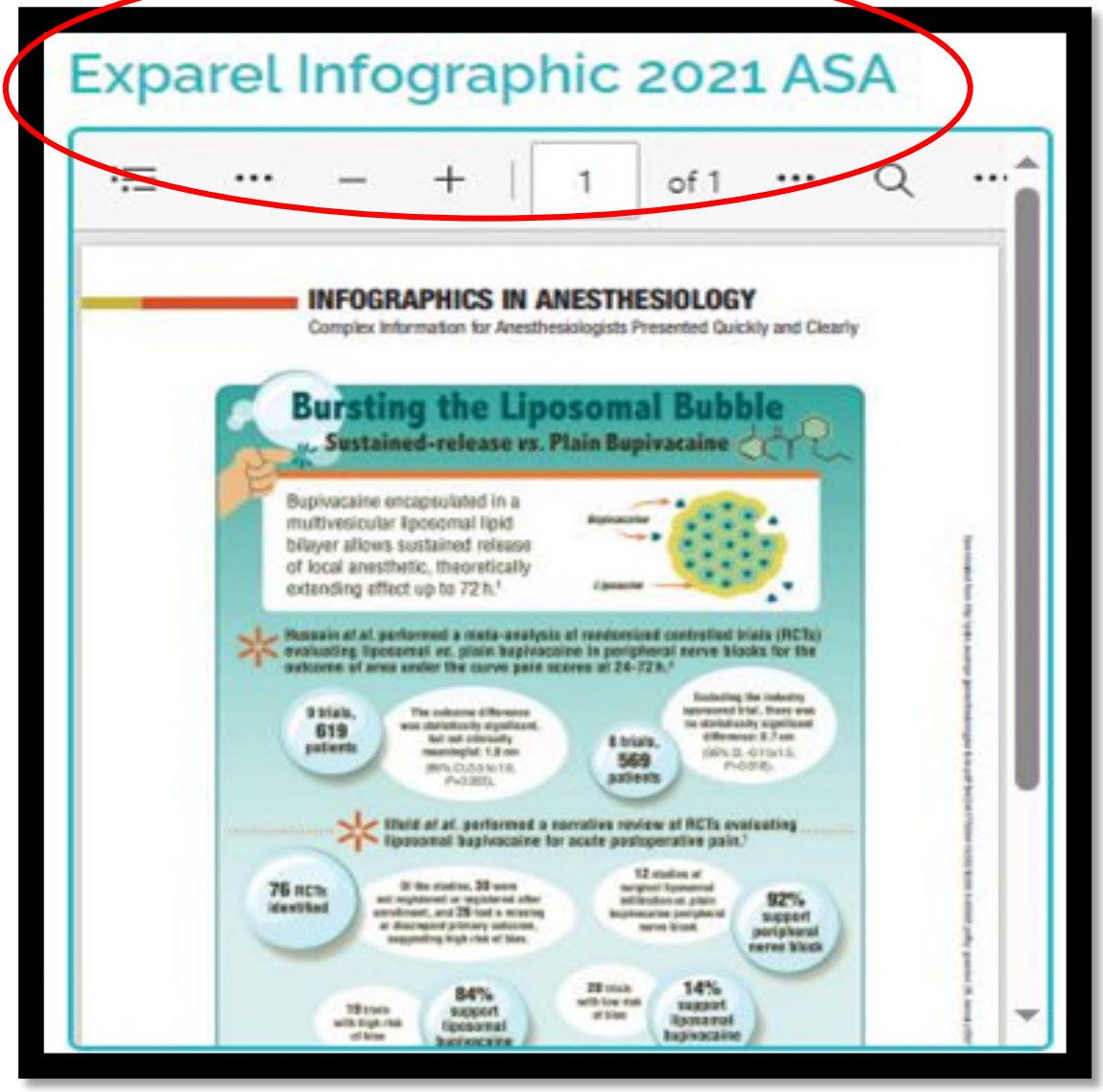
94. The leading commercially available product in the Post-Surgical Non-Opioid Regional Analgesia Category is EXPAREL®. Defendants advertise Ventis' Unapproved

Compounded Drug Cocktail by claiming that the Endura-Kit product is "clinically significant over other commercially available products." An example of this advertising is set forth below:

95. The Endura-Kit product is not "clinically significant" over EXPAREL®. Indeed, there are no clinical studies whatsoever supporting this Unapproved Compounded Drug Cocktail, which has never been reviewed or approved by the FDA.

96. Still further, Defendants claim that the Unapproved Compounded Drug Cocktail products they are advertising, offering for sale, and selling are superior to liposomal bupivacaine products like EXPAREL®. An example of such advertising, identified by Defendants as the "Exparel Infographic" on Ventis' website,[14] is set forth below:

[14] *See* Ventis Pharma, https://www.ventispharma.com/news (last visited Nov. 1, 2023).



97. Without any basis in fact, Defendants, in such advertising, make direct and false comparisons of Ventis' Unapproved Compounded Drug Cocktail with the studies and data for EXPAREL®, communicating that the products are equivalent or are otherwise substitutable.

98. On information and belief, Defendants have communicated similar false and misleading statements about Ventis' Unapproved Compounded Drug Cocktail through sales meetings with providers.

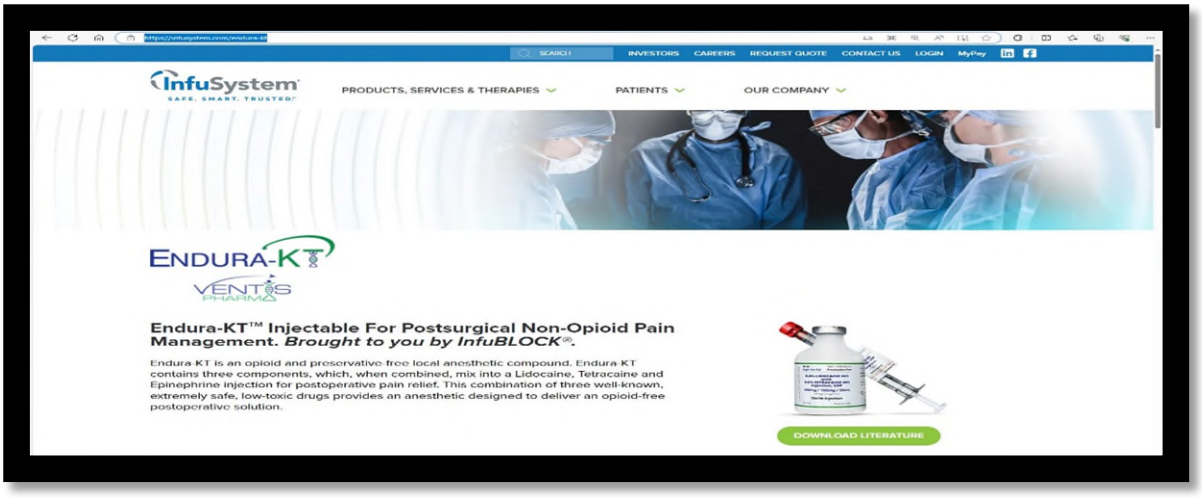
99. On information and belief, on sales calls and presentations to healthcare providers, InfuSystem's sales team claims that each component of the Endura-Kit product has supposedly obtained FDA approval.

100. On information and belief, InfuSystem's representatives have claimed, without any basis in fact, that the Endura-Kit product provides over 60 hours of pain relief in the peripheral nerve space and 48-72 hours of pain relief in the cavity space (thereby claiming the product is comparable to EXPAREL®'s clinically-proven pain relief for up to 72 hours).

101. Finally, on information and belief, InfuSystem has represented to healthcare providers that current and ongoing studies have confirmed the efficacy and superiority of the Endura-Kit Unapproved Compounded Drug Cocktail over FDA-approved EXPAREL®. There are, however, no such ongoing studies. On information and belief, there are no current and ongoing clinical trials comparing the Endura-Kit product to any other product in the Post-Surgical Non-Opioid Regional Analgesia Category, let alone to EXPAREL®, as claimed by InfuSystem in its comparative claims.

102. On information and belief, the Endura-Kit Unapproved Compounded Drug Cocktail advertised, offered for sale, and sold by Ventis and InfuSystem has recently been rebranded "Endura-KT" as promoted on the InfuSystem website[15]:

[15] *See Endura-KT Non-Opioid Pain Management*, https://infusystem.com/endura-kt (last visited Nov. 1, 2023).



103. Healthcare providers and consumers reasonably rely on Defendants' false and misleading statements in purchasing the Enduracaine, Endura-Kit, and/ or Endura-KT Unapproved Compounded Drug Cocktail products instead of EXPAREL®.

104. In conjunction with their false and misleading statements and advertisements, Defendants intentionally sell the Enduracaine and Endura-Kit (and/ or Endura-KT) product at prices well-below EXPAREL® to compete against Pacira and steal its market share by further inducing providers and hospitals to buy their Unapproved Compounded Drug Cocktails.

105. Because the Enduracaine and Endura-Kit (and/ or Endura-KT) products were produced in circumvention of the FDA new drug approval process and attendant investment of time and capital, Defendants can price their Unapproved Compounded Drug Cocktails well below EXPAREL®.

106. On information and belief, Defendants have sold thousands of units of the Enduracaine and Endura-Kit (and/ or Endura-KT) products to healthcare providers and hospitals in the United States.

107. By using their false and misleading statements and advertisements that the Enduracaine and Endura-Kit (and/ or Endura-KT) products are generic to or substitutable for

FDA-approved EXPAREL®, that the products have been approved by the FDA as safe and effective, and that (notwithstanding the fact that there is absolutely no data whatsoever on the Unapproved Compounded Drug Cocktails, before the FDA or elsewhere) current and ongoing studies have confirmed the efficacy and superiority of the Endura-Kit Unapproved Compounded Drug Cocktail over FDA-approved EXPAREL®, and also by pricing their Unapproved Compounded Drug Cocktail products below the price of EXPAREL®, Defendants have engaged in false and misleading advertising to lure health care providers to purchase their unlawful drugs instead of EXPAREL®, to Pacira's detriment.

COUNT I
(False And Misleading Advertising And Promotion Under 15 U.S.C. § 1125(a)(1)(B))
(As To Both Defendants)

108. Pacira realleges and incorporates by reference the allegations set forth in Paragraphs 1 through 107 of this Complaint as if fully set forth herein.

109. Defendants' practices, as described in this Complaint, constitute false and misleading advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

110. Defendants have violated the Lanham Act by using false and misleading advertisements and marketing claims, or impliedly false advertising and marketing claims, that misrepresent the nature, characteristics, and/ or qualities of Ventis' Unapproved Compounded Drug Cocktails sold in competition with EXPAREL®.

111. Among other false and misleading statements, Defendants have claimed that:

- **"Endura-Kit" and/ or "Endura-KT" are generic to or substitutable for EXPAREL®.** These statements are literally false or impliedly false because these Unapproved Compounded Drug Cocktails, which are not FDA-approved, do not have technology causing the bupivacaine to be released over time, and do not provide pain relief for up to 72 hours;

- **"Endura-Kit" and/ or "Endura-KT" are "exempt" from FDA approval and are "produced following cGMP manufacturing guidelines under 503B outsourcing standards overseen by the FDA."** These statements are literally false or impliedly false because the FDA does not oversee the production of these Unapproved Compounded Drug Cocktails, and they do not satisfy the 503B exemption requirements;

- **"Endura-Kit" and/ or "Endura-KT" are "made from a combination of currently FDA approved USP products."** These statements are literally false or impliedly false because the FDA has not approved the use of the drugs as combined in these Unapproved Compounded Drug Cocktails;

- **"Endura-Kit" and/ or "Endura-KT" are "considered safe and acceptable for use," provide an "extended duration" of pain relief compared to other drugs, have a "quick onset," and are "long lasting."** These statements are literally false or impliedly false because they suggest that these Unapproved Compounded Drug Cocktails have been reviewed or approved by the FDA, or have undergone clinical trial testing for safety and efficacy, which they have not; and

- **Current and ongoing studies have <u>confirmed</u> the efficacy and superiority of "Endura-Kit" and/ or "Endura-KT" as compared to EXPAREL®.** These statements are literally false or impliedly false because Ventis has not commissioned any current ongoing clinical trials to confirm the supposed efficacy and superiority of these Unapproved Compounded Drug Cocktails as compared to competitors, including EXPAREL®.

112. Defendants, if not enjoined by this Court, are likely to deceive purchasers of Ventis' Unapproved Compounded Drug Cocktails, prescribing physicians, patients, and members of the general public.

113. The above-described acts of Defendants have irreparably harmed Pacira and, if not enjoined, will continue to irreparably harm, Pacira.

114. The above-described acts of Defendants have irreparably harmed the public interest, and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

115. As a direct and proximate result of Defendants' knowing and willful false and misleading statements, false advertising, and wrongful acts of unfair competition, Pacira has

suffered and will continue to suffer injury in fact and actual damages, including lost business, market share, sales, revenue, and profits.

116. However, Pacira's remedies at law are not adequate to compensate for all the injuries inflicted by Defendants. Accordingly, Pacira is entitled to entry of preliminary and permanent injunctive relief requiring Defendants to cease their false and misleading advertising, promotion, and unfair competitive practices.

117. If not restrained, Defendants will have unfairly derived, and will continue to unfairly derive, income, profits, and business opportunities as a result of their acts of false and misleading advertising and unfair competition.

118. By reason of the foregoing, Pacira is entitled to injunctive relief as well as actual damages, treble damages, disgorgement of Defendants' profits, the costs of this action, and attorney's fees pursuant to 15 U.S.C. § 1117, as well as all other available remedies as set forth in its Prayer for Relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Pacira BioSciences, Inc., prays for this Court to enter judgment against Defendants, granting the following relief:

1. An order:

- Preliminarily and permanently enjoining Defendants and their agents, employees, contractors, successors, and assigns, and all other persons acting in concert with or in conspiracy with or affiliated with them, from falsely advertising or stating that Ventis' Endura-Kit, Endura-KT, and/ or Enduracaine are 503B exempt, approved by the FDA, have been the subject of clinical trials, or achieve certain therapeutic outcomes; and

- Requiring Defendants and their agents, employees, contractors, successors, and assigns, and all other persons acting in concert with or in conspiracy with or affiliated with them, to engage in corrective advertising by informing patients and providers that Ventis' Endura-Kit, Endura-KT, and/ or Enduracaine are not and have not been 503B exempt, approved by

the FDA, or the subject of clinical trials, and do not achieve certain therapeutic outcomes;

2. Monetary relief, in the form of an award of Defendants' profits, for their false and misleading advertising and that this monetary relief be increased due to Defendants' willfulness pursuant to 15 U.S.C. § 1117 and as otherwise permitted by law;

3. Disgorgement of Defendants' profits by which they have been unjustly enriched because of their unlawful actions;

4. Actual damages in an amount to be proven at trial pursuant to 15 U.S.C. § 1117 and as otherwise permitted by law;

5. Costs of suit herein pursuant to 15 U.S.C. § 1117 and as otherwise permitted by law;

6. Reasonable attorney's fees pursuant to 15 U.S.C. § 1117 and as otherwise permitted by law;

7. Pre-judgment, post-judgment, and other interest on all monetary damages, as permitted by law; and

8. Any and all such further relief that the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Pacira demands a trial by jury in this action on all issues so triable as of right.

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